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ZARA, JANE J

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/632,639
Filing Date: July 31, 2000
Appellant(s): SAMPSON ET AL.

Cynthia J. Lee
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5-9-05.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

This appeal involves claims 1-26.

(4) Status of Amendments After Final

The amendment after final rejection filed on 11-8-04 has not been entered.

This appeal involves claims 1-26.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-26 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,912,340	Kutyavin et al.	6-1999
6,569,630	Vivekananda et al.	5-2003

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-26 rejected under 35 U.S.C. 102(e). This rejection is set forth in a prior Office Action, mailed on 10-2-03 and 12-20-4.

(11) Response to Argument

The rejection of claims 1-5, 7-17 and 19-26 under 35 U.S.C. 102(e) as being anticipated by Vivekananda et al is hereby withdrawn in light of Appellants' arguments filed 5-9-05.

Claims 1-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Kutyavin et al. (henceforth "Kutyavin") for the reasons of record set forth in the Office actions mailed 10-2-03 and 12-20-04.

Appellants' arguments filed 5-9-05 have been fully considered but they are not persuasive. Appellants argue that claims 1-26 recite steps or features not taught or

suggested by Kutyavin (USPN 5,912,340), and therefore Kutyavin does not properly anticipate the claimed invention. Applicants argue that no teaching is found in Kutyavin for a method where one must specifically employ a pair of nucleotide analogs. Appellants also assert that Kutyavin addresses the specific problem of facilitating strand invasion of a duplex nucleic acid molecule and therefore discloses the key feature that the matched set of oligonucleotides must be unable to base pair with each other, but does not teach or suggest a method of producing nucleic acid molecules that contain pairs of nucleotides such that the nucleic acid molecules are unable to base pair with each other and are individually unable to form intramolecular base pair interactions. The distinction between Kutyavin and the instantly claimed invention, according to Appellants, is that the instant invention claims nucleotides that include pairs of complementary nucleotide with reduced ability to form base pairs, but can form a base pair with its complementary naturally occurring nucleotide, while Kutyavin does not teach the limitation of incorporating pairs of nucleotide analogs into the same nucleic acid molecule.

Contrary to Appellants' arguments, Kutyavin teaches methods of synthesizing nucleic acid molecules comprising the incorporation of pairs of nucleotide analog precursors with a reduced ability to form base pairs with each other (*e.g.* 2-aminodeoxyadenosine 5'-triphosphate, 2-thiodeoxythymidine or cytidine 5'-triphosphate, pyrrolo pyrimidine triphosphate, inosine triphosphate), employing such enzymes well known in art as polymerases, as claimed in the instant invention (see the abstract; col.

2, line 33- col. 9, line 53; esp. text in col. 4; claims 1-20 and col. 5, col. 34, lines 53- 67; col. 18 and 22-23; claims 1-20, 23-25).

Kutyavin specifically discloses a method of producing nucleic acid molecules that have both a reduced ability to form stable hydrogen bonded base pairs with each other, and have a reduced ability to form stable hydrogen bonded intramolecular base pair interactions. That is, as claimed in the instant invention, Kutyavin teaches nucleic acid molecules with a reduced ability to form both intermolecular and intramolecular hydrogen bonded base pairs, with both members of the non-hydrogen bond forming nucleotide pair present in each nucleic acid molecule: See, for instance, Kutyavin's abstract: "The ODNs include modified bases of such nature that the modified base forms a stable hydrogen bonded base pair with the natural partner base, but does not form a stable hydrogen bonded base pair with its modified partner. This is accomplished when in a hybridized structure the modified base is capable of forming two or more hydrogen bonds with its natural complementary base, but only one hydrogen bond with its **modified partner**. Due to the lack of stable hydrogen bonding with each other, **the matched pair of oligonucleotides** have a melting temperature under physiological or substantially physiological conditions of approximately 40° C or less. However **each of the matched ODN pair** of the invention forms a substantially stable hybrid with the target sequence in each strand of the duplex nucleic acid. The hybrids of the target duplex nucleic acids formed with the **ODN pairs** of the invention are useful for..." (emphasis added).

Again in col. 1, lines 51-53, the incorporation of matched, modified base pairs is stressed: "Thus, the **matched pair of oligonucleotides** in accordance with the present invention do not form substantially stable hydrogen bonded hybrids with one another, as manifested in a melting temperature... of approximately 40° C or less." The incorporation of both members of a non-hydrogen bond forming nucleotide pair, to be present in each nucleic acid molecule produced, is disclosed throughout the Kutyavin reference, e.g. in col. 2, lines 14-23: "[A] key feature of the SBC ODNs of the present invention is that **each one of a matched pair of the SBC ODNs** is complementary... to one target sequence in duplex nucleic acid... and **each one of the matched pair of the SBC ODNs** forms a stable hydrogen bonded hybrid with one strand of the target sequence." (emphasis added).

These "SBC ODNs," or "selective binding complementary ODNs" disclosed by Kutyavin, refer to those ODNs that contain nucleotide analog pairs, including inosine triphosphate for G and pyrrolo-pyrimidine triphosphate for C or containing 2-thiothymidine triphosphate for T and 2-aminoadenosine triphosphate for A as specifically claimed in the instant invention (see text in col. 22 of Kutyavin: "Several oligonucleotides were prepared containing dI for dG, dP for dC, or containing d2-sT for dT and d2-amA for dA."

See also Table 1 and Table 2, cols. 23-24 of Kutyavin for specific examples of nucleic acid molecules that have the instantly claimed modified base pairs incorporated into a single nucleic acid strand. The text in col. 23, lines 30-32 explains the existence of these pairs in a single strand: "The pair of SBC ODNs shown as Hybrid IV in Table 1

comprises two 28-mer sequences where each of the natural dG and dC nucleotides is replaced with dI and dP, respectively." And in col. 24, lines 25-26: "...SBC(V) and SBC(VI) are modified so that each dA and each dT is replaced with the d2amA and d2sT, respectively." So, contrary to Appellants' assertions, no distinction exists between the instantly claimed invention and Kutyavin because both teach the incorporation of non-hydrogen bond forming nucleotide pairs in the same nucleic acid molecule.

Appellants argue that Kutyavin does not properly anticipate the claimed invention because Kutyavin poses the problem of facilitating strand invasion of a duplex nucleic acid molecule. Appellants also contrast the teaching of Kutyavin with the instant disclosure by asserting that the methods disclosed by Kutyavin, which are identical to the instantly claimed methods (*e.g.* see col. 4-8, which describes a method of synthesizing nucleic acid molecules by providing the precursor nucleotides identical to those instantly claimed), produce a single strand comprising these modified nucleotides, and not two strands with complementary nucleotide pairs with reduced ability to form stable hydrogen bonds. Contrary to Appellants' assertions, the methods taught previously by Kutyavin, of producing the nucleic acid strands comprising modified nucleotides within the nascent nucleic acid molecules are identical to those of the instant invention. Therefore, the instant 102 rejection, based on the prior disclosure of the methods claimed by or Kutyavin, is maintained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

JZ
July 14, 2005

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